

**REMARKS**

This is a full and timely response to the Office Action mailed October 27, 2004.

By this Amendment, claim 1 has been amended to more particularly define the present invention, and claim 2 has been canceled without prejudice or disclaimer to its underlying subject matter. Further, new claims 13-22 have been added to direct to subject matter canceled in amended claim 1. Support for the claim amendments can be found variously throughout the specification and the original claims, see for example, pages 2, 3 and 8. In particular, specific support for the terms "*intact and unlysed*" can be found on page 8, line 17, to page 9, line 1, of the specification which states that

*"In the concrete, no following pretreatment is required; the nucleic acid inclusion body is **decomposed** using an enzyme, a surfactant, a chaotropic agent, or the like, and then nucleic acids are extracted from the decomposed product of the nucleic acid inclusion body using phenol, phenol/chloroform or the like. Further, pretreatment using an ion-exchange resin, a glass filter, glass beads, a reagent having an effect of agglutinating proteins, or the like is not required in the step of the nucleic acid extraction".*

Thus, claims 1, 3-11 and 13-22 are pending in this application.

In view of this Amendment, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

**Rejection under 35 U.S.C. §112**

Claims 1-11 are rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. Applicant respectfully traverses this rejection.

However, in order to expedite prosecution, Applicant has amended claim 1 to address the Examiner's concerns. Specifically, claim 1 has been amended to replace the term "*nucleic acid inclusion body*" with "*a living body sample comprising a cell, fungus, bacterium, or virus*". Such an amendment is supported by the disclosure (see page 8) of the specification and original claim 2.

Thus, withdrawal of this rejection is respectfully requested.

**Rejections under 35 U.S.C. §103**

Claims 1-9 and 11 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ivanov et al. (U.S. Patent 6,183,998) in view of Sandhu et al. (U.S. Patent 5,707,802). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, the cited references, in combination, must teach or suggest all of the claim limitations (see §2142 of the Manual of Patent Examining Procedure). Here, in this case, the combination of Ivanov et al. and Sandhu et al. fail to teach or suggest the limitations presented in amended claim 1 of “*adding a living body sample comprising a cell, fungus, bacterium, or virus to an amplification reaction solution comprising a polyhydric alcohol and ammonium sulfate*” and “*wherein said cell, fungus, bacterium, or virus of said living body sample is intact and unlysed without extracting and/or purifying said nucleic acid from inside said cell, fungus, bacterium, or virus, when said living body sample is added to the amplification reaction solution*”. Also, the combination of Ivanov et al. and Sandhu et al. fail to teach or suggest the limitation of new claim 13 of “*wherein said cell, fungus, bacterium, or virus is added to the amplification reaction solution intact and unlysed without extracting and/or purifying said nucleic acid from inside said cell, fungus, bacterium, or virus*”.

In other words, the present invention is directed to a method for synthesis of nucleic acids where the cell, fungus, bacterium, or virus, or a sample (such as a living body sample) comprising such cell, fungus, bacterium, or virus are added to the amplification reaction solution while the cell, fungus, bacterium, or virus are still intact and unlysed. As such, the nucleic acid from inside the cell, fungus, bacterium, or virus has not been extracted and/or purified upon being added to the amplification reaction solution which is why the specification states that no purification or pretreatment step of the cell, fungus, bacterium, or virus is required.

In contrast to the present invention, Sandhu et al. teaches performing PCR on a “*fungus culture*” which is clearly distinguishable from performing PCR on a “*living body sample*” as in amended claim 1. Further, Ivanov et al. and Sandhu et al. teach the extraction and purification of nucleic acid prior to amplification. In the examples of Ivanov et al. (see examples 7 and 8, columns 11-13, and example 15, columns 16-18), Ivanov et al. clearly disclose that human genomic DNA from human whole blood and RNA from HeLa cells are extracted and purified using commercial kits (QIAamp<sup>®</sup> Blood Kit and RNasy<sup>®</sup> Maxi Kit from Qiagen). Likewise, in Sandhu et al. a loopful of fungal culture was scraped off a culture plate using a sterile inoculation loop and added to one milliliter of sterile water in a 1.5 ml microcentrifuge

tube. This tube was then *placed in a boiling water bath for 20 minutes in order to lyse the fungus and release DNA of the cells*. In other words, the sample in Sandhu et al. undergoes a pretreatment process of extracting (i.e. releasing) the nucleic acid from the fungus before being added to the amplification reaction solution.

Thus, since Ivenov et al. and Sandhu et al., in combination, fail to teach or suggest all the claim limitations, this rejection cannot be sustained and should be withdrawn.

Claim 10 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Ivanov et al. (U.S. Patent 6,183,998) in view of Sandhu et al. (U.S. Patent 5,707,802) and in further view of Yamada et al. (U.S. Patent 5,369,096) or Kelly et al. (U.S. Patent 4,978,757) or Holliger et al. (U.S. Patent 4,820,309) or Ukachi et al. (U.S. Patent 4,683,280) or Endo et al. (U.S. Patent 4,368,314) or Taniguchi et al. (U.S. Patent 6,054,501). Applicant respectfully traverses this rejection. Since the deficiency in Ivanov et al. and Sandhu et al. (of failing to teach or suggest the limitation “*wherein said cell, fungus, bacterium, or virus, or said living body sample (comprising said cell, fungus, bacterium, or virus) is added to the amplification reaction solution intact and unlysed without extracting and purifying said nucleic acid from inside said cell, fungus, bacterium, or virus*”) is not cured by the teaching and suggestions of the other cited references, this rejection cannot be sustained for the same reasons as noted above, and should be withdrawn.

**CONCLUSION**

For the foregoing reasons, all the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

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Respectfully submitted,

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